

Application No. 10/786,186
Supplemental Amendment "B" dated April 5, 2006
Reply to Office Action of December 23, 2005

REMARKS

Claims 1-17, 20 and 25-28 remain pending in the application, wherein claims 1, 14, and 25 have been amended. No claims were added or cancelled by this amendment.

As previously explained, the claimed suture separation devices are configured to reliably maintain a plurality of tensioned suture strands extending from a bone tunnel in a desired spaced apart relationship on either side of the bone tunnel. This facilitates insertion of an interference screw into the bone tunnel to fix a soft tissue graft attached to the suture strands. Because the suture strands are under relatively high tension just before fixing the soft tissue graft within the bone tunnel, the tensioned suture strands may not remain separated in the desired space-apart relationship unless the suture separation device includes recesses or protrusions that are specifically adapted for this purpose. For example, if the recesses provided a gradual ramp of say 45° upon which the tensioned sutures could slide up and out of the recess, the tensioned sutures may not reliably remain in the desired spaced-apart relationship on either side of the bone tunnel.

In view of the foregoing, claim 1 was amended to specify that the means for separating and organizing a plurality of tensioned suture strands is specifically adapted for "reliably maintaining the tensioned suture strands in a desired spaced-apart orientation on either side of the bone tunnel when said body means is attached to a graft tensioning device during joint repair surgery in order that such tensioned suture strands do not inadvertently slip out and move towards each other so as to block insertion of an interference screw therebetween". Support for this limitation is shown in Figures 7, 8 and 9. Claims 14 and 25 were similarly amended. The claims as now amended exclude devices that are not specifically adapted to reliably maintain tensioned suture strands in the desired spaced-apart relationship so as to facilitate insertion of an interference screw therebetween during joint repair surgery.

Claim 14 was further amended to specify that each attachment passage or recess has "a size and shape so as to reliably mate with the corresponding post of a graft tensioning device so as to reliably hold the body from inadvertently slipping off the graft tensioning device when the device is used to separate tensioned sutures during use". Support for this additional limitation is shown in Figure 7.

As discussed in the previous amendment, Jain (US 5,207,703) discloses a suture organizer for preventing untensioned sutures from becoming entangled during an operation. Jain does not disclose "means for removably attaching said body means to a graft tensioning device"

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as recited in claim 1, or the attachment passages or recesses of claim 14. Jain is therefore incapable of performing the function of the devices of claims 1 and 14. Jain also lacks the structural features of the device of claim 25 and is therefore incapable of providing its function.

As previously discussed, one of skill in the art would not have been motivated to combine Jain with Filhol (US 4,692,116), which discloses a dental pin. The devices of Jain and Filhol are non-analogous to each other and cannot be combined without destroying the intended functionality of each. For example, for the device of Jain to function properly, it must be at least approximately 6-12 inches long as shown in the drawings. The dental pin of Filhol, on the other hand, must be tiny enough to be inserted into a tooth. It is never obvious to modify a device in a manner that renders it unsuitable for its intended purpose. MPEP § 2143.01(V). The same analysis is true for any alleged combination of Jain and Venturini et al. (US 6,749,611), which discloses a bone screw.

During a telephonic interview with Examiner Kim on April 4, 2006, the embodiments defined in claims 1 and 14 were discussed in relation to the bone screw of Venturini et al. Upon review of the bone screw of Venturini et al., it become clear that the shallow, elongated and gently sloped "flats 8" and "flats 10" of the bone screw are not capable of reliably maintaining a plurality of tensioned suture strands extending from a bone tunnel in a desired spaced apart relationship on either side of the bone tunnel. Instead, sutures under relatively high tension would likely slide up and out of the gently ramped sides of "flats 8" and "flats 10". For this reason alone, claims 1 and 14 define a device that is neither taught or suggested in Venturini et al.

Moreover, it is important to note that "flats 8" and "flats 10" are specifically designed to engage the socket of a tool such as a T-wrench used to screw the bone screw of Venturini et al. into a bone. Col. 4, ll. 20-22. The plurality of "flats 8" and "flats 10" are in a predetermined spaced apart relationship so that the bone screw can be cut along its length and still provide a shank that can be gripped by a tool such as a T-wrench. Col. 4, ll. 48-59. Thus, it would be contrary to Venturini et al. to redesign the "flats 8" and "flats 10" in a manner that may prevent the shank from being gripped by a tool used to grip and screw the bone screw. It is never obvious to modify a device in a manner that renders it unsuitable for its intended purpose. MPEP § 2143.01(V). In any event, because the bone screw of Venturini et al. has absolutely nothing at all to do with maintaining tensioned suture strands in a desired spaced apart

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relationship relative to a bone tunnel, one of skill in the art would not have been motivated to modify the "flats 8" and "flats 10" to perform this function.

The "flat 8" and "flat 10" of Venturini et al. are likewise not designed to removably attach a body means or body of a suture separation device to a graft tensioning device. The "flats 8" and "flat 10" are both shallow and elongated to facilitate gripping by a tool such as a T-wrench. Because the bone screw of Venturini et al. has absolutely nothing at all to do with being attached to a graft tensioning device, one of skill in the art would not have been motivated to modify the "flats 8" and "flats 10" to perform this function. Claims 1 and 14 are further patentable over Venturini et al. for this additional reason.

The same analysis applies to the dental pin and holder of Filhol. The serpentine shank of the dental pin and holder provides recesses and gentle 45° ramps that would likely permit or cause sutures under relatively high tension to slide up and out of the recesses comprising the serpentine shank. For this reason alone, claims 1 and 14 define a device that is neither taught or suggested in Filhol. More fundamentally, the Filhol device must have a size that permits it to be inserted into a tooth. However, a device this small could not be used to feasibly maintain tensioned sutures in a desired spaced apart relationship in either side of a bone tunnel. Because enlarging the Filhol device and then modifying it to provide the function recited in claim 14 would likely render it unsuitable for its intended purpose, one of skill in the art would not have been motivated to make this change. It is never obvious to modify a device in a manner that renders it unsuitable for its intended purpose. MPEP § 2143.01(V).

Finally, Applicants acknowledge that many of the features that distinguish the claimed devices over the cited art are functional in nature. The MPEP favorably considers functional language that further defines the scope of claimed invention:

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA).

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient or step. . . .

It was held that the limitation used to define a radical on a chemical compound as "incapable of forming a dye with said oxidizing developing agent" although functional,

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was perfectly acceptable because it set definite boundaries on the patent protection sought. *In re Barr*, 444 F.2d 588, 170 USPQ 22 (CCPA 1971).

In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly. *In re Venezia*, 530 F.2d. 956, 189 USPQ 149 (CCPA 1976).

MPEP § 2173.05(g). Thus, functional language that more particularly defines how structural elements are arranged or operate is appropriate and further limiting, and it must be considered by the PTO when examining a claim.

The situation in *In re Venezia* is similar to the present case. In *Venezia*, the claims contained limitations that set definite boundaries as to how the component parts would function during use, even though the claims were directed to a "kit of component parts capable of being assembled" in a specific fashion, not a method of use. In the present case, the suture retention recesses, protrusions or means are specifically adapted to reliably maintain tensioned suture strands in a desired spaced apart relationship on either side of a bone tunnel to facilitate insertion of an interference screw into the bone tunnel. Structures that cannot provide this function are excluded from within the scope of the claims. Because the functional limitations recited in claims 1, 14 and 25 further limit the scope of the claims, they are not mere intended uses but narrowing limitations that must be considered according to MPEP § 2173.05(g) and the court in *Venezia*, *Barr* and *Swinehart*.

In view of the foregoing, Applicants submit that the claims as amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 5th day of April 2006.

Respectfully submitted,



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